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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,153	12/02/2000	Hiroshi Nomura	QSTR-01.0	3652
7:	590 12/19/2002			
Robert J. Petersen QuestStar Medical, Inc. 10180 Viking Drive			EXAMINER	
			CROSS, LATOYA I	
Eden Prairie, MN 55344			ART UNIT	PAPER NUMBER
			1743	7
			DATE MAILED: 12/19/2002	5

Please find below and/or attached an Office communication concerning this application or proceeding.

		A			
	Application No.	Applicant(s)			
Office Action Summary	09/728,153	NOMURA ET AL			
Office Action Summary	Examiner	Art Unit			
The MAU INC DATE of this communication and	LaToya I. Cross	1743			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status					
1) Responsive to communication(s) filed on <u>02 D</u>	<u> Pecember 2000</u> .				
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ Thi	s action is non-final.				
3) Since this application is in condition for allowa					
closed in accordance with the practice under <i>I</i> <b>Disposition of Claims</b>	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.			
4) Claim(s) 1-15 is/are pending in the application					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-15</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
9) The specification is objected to by the Examiner.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the	•	, ,			
11) The proposed drawing correction filed on is: a) □ approved b) □ disapproved by the Examiner.  If approved, corrected drawings are required in reply to this Office action.					
12) The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. §§ 119 and 120					
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:					
1. Certified copies of the priority documents	s have been received.				
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).					
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.					
Attachment(s)					
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2</li> </ol>	5) Notice of Informal F	(PTO-413) Paper No(s) Patent Application (PTO-152)			

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## **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 1, 2 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,203,850 to Nomura.

Nomura teaches porous polymeric materials that have been surface treated. The surface treatment involves exposing the surfaces to a glow discharge gas plasma (col. 4, lines 33-38). The gas plasma is gas or gas mixture containing at least one saturated hydrocarbon in combination with a source of oxygen (col. 5, lines 49-54). The saturated hydrocarbon is a low molecular weight alkane, chosen from methane, ethane or propane (col. 6, lines 5-8). The source of oxygen may be air (col. 5, lines 52-54). The porous surfaces to be treated include porous materials, such as nylons, in the form of sheets, films, fibers, etc. (col. 5, lines 8-20). In the examples, Nomura shows several porous materials being treated using glow discharge gas plasma. The materials are disclosed as having stabilized surface hydrophilicity and reduced adsorption characteristics.

It is noted that the Nomura reference does not specifically that the porous materials are wicks; however, wicks are defined as materials capable conveying a liquid by way of capillary action. Nomura teaches that the porous materials have absorption capacities (col. 5,l ines 31-37), thus the materials would be suitable at wicking materials.

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With respect to the wicking rate recited in claim 1, such a property would be inherent to the surface treated materials of Nomura, since Nomura uses the same gas plasma treatment process claimed by Applicants.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b), in view of the teachings of Nomura.

## Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 3, 4 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura in view of US Patent 6,040,195 to Carroll et al.

Nomura is described in detail above.

Nomura fails to teach a diagnostic device for analyzing an analyte in a physiological fluid wherein the device contains a surface treated wicking material.

Carroll et al teach a diagnostic device for analyzing fluids such as whole blood. The device contains a reagent containing layer (40) and a separating layer (30). These layers are sandwiched within a holder made from upper and lower supports (12, 13). The reagent layer (40) contains reagents for the detection of various analytes in blood. The separation layer (30) is a woven cotton/polyester fabric. The fabric is surface treated to minimize adsorption of plasma and allow more plasma to reach the reagent layer. See col. 6, lines 32-57. With respect to the method of analyzing for the presence of an analyte, Carroll et al teach that a sample of

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blood is disposed on the separating layer (30) and then wicks to the reagent containing layer (40), where determination of the presence of the analyte takes place.

Carroll et al seeks to minimize adsorption of blood samples to lower the amount of sample needed to conduct the analysis tests. Nomura teaches that by using glow discharge gas plasma surface treatments, the surfaces of porous materials exhibit remarkably reduced protein adsorption. Nomura also teaches that glow discharge gas plasma reducing fouling tendencies when exposed to proteinaceous fluids. Thus, it would have been obvious to one of ordinary skill in the art to modify the diagnostic device of Carroll et al by surface treating the separating layer (30) with glow discharge gas plasma as disclosed in Nomura et al to lower plasma absorption and reduce fouling.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teaching of Nomura and Carroll et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Technology Center 1700

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